

## REMARKS

Applicant amended claims 121, 126, 204, 206, 208, and 210 and added new claims 211-214 to further define Applicant's claimed invention. Support for dependent claims 211-214 is found at least on page 5, line 22 to page 6, line 1 of the specification.

In the Office Action, the Examiner rejected claims 204, 205, and 208-210 under 35 U.S.C. § 112, second paragraph, as being indefinite. For the Examiner's rejection of claims 204, 208, and 210, Applicant is submitting in an IDS concurrently filed herewith, U.S. Patent No. 6,087,555 issued July 11, 2000 to Dunstan et al. describing the phrase "genes coding." (See, for example, col. 8, lines 45-49). It is submitted that one skilled in the art would appreciate and understand "genes coding" in the context of the invention as demonstrated by the teachings of Dunstan et al.

For the Examiner's rejection of claims 205 and 209, the Examiner is referred to the specification at page 9, lines 9-11; page 19, line 19 to page 20, line 3; and Fig. 1 for examples of support for the subject matter of claims 205 and 209. Figs. 1 and 2 show an exemplary chamber between upper and lower surfaces 106, 108, respectively, of implant 100 and openings 112, 114, and 116.

The Examiner rejected claims 204, 208, and 210 under 35 U.S.C. § 101 as being directed to non-statutory subject matter. Applicant respectfully disagrees with the Examiner's contention that a naturally occurring substance cannot be claimed in combination with the claimed invention. It is well known in the art of spinal surgery to use bone or a bone composition in combination with an implant to facilitate fusion. Applicant is claiming the combination of the claimed implant with bone, not just bone by itself. To facilitate prosecution of this application, Applicant has nonetheless amended claims 204, 208, and 210 to recite the step of combining the implant with "harvested

bone.” Applicant submits that claims 204, 208, and 210 are directed to statutory subject matter.

The Examiner rejected claims 121, 124-126, 129, 130, and 203-210 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,258,125 to Paul et al. Independent claim 121 recites the step of forming a plurality of surface projections having a base, at least two of which have “side facets having a maximum width therebetween at the base.” The base of one of the at least two surface projections is “spaced apart from a base of another of said surface projections by a distance no greater than one-half the maximum width of said at least one of said at least two surface projections.” Paul does not teach or suggest a method of forming a plurality of surface projections as recited in Applicant’s claim 121.

Independent claim 126 recites the step of forming surface projections as part of the upper and lower surface of an implant, the surface projections having side facets “having at least a first portion in a plane passing through and being at an angle to the mid-longitudinal-axis of the implant.” Paul does not teach nor suggest a method of forming a plurality of surface projections as claimed in Applicant’s claim 126.

The Examiner contends that a “longitudinal axis” can be “the longest line between the diagonal corners of the implant.” (See, Office Action, page 3, paragraph 4). Applicant respectfully disagrees with the Examiner’s interpretation of the phrase “longitudinal axis.” Nonetheless, Applicant has amended claim 126 to recite a “mid-longitudinal axis” that passes “through the leading and trailing ends” of the implant.

Applicant submits that independent claims 121 and 126 are allowable over Paul and that dependent claims 124, 125, 129, 130, and 203-210 dependent from one of independent claims 121 and 126, or claims dependent therefrom are allowable at least

due to their dependency from an allowable independent claim.

The Examiner also rejected claims 121, 124-126, 129, 130, and 203-210 under 35 U.S.C. 102(e) as being anticipated by WO Publication No. 98/58604 to Tsitsopoulos. Applicant submits that this rejection is improper. The Examiner is referred to the Notice entitled "Examination Guidelines for 35 U.S.C. § 102(e), as amended by the American Inventors Protection Act of 1999, and further amended by the Intellectual Property and High Technology Technical Amendments Act of 2002, and 35 U.S.C. § 102(g)," (hereinafter "the Notice"). In particular, section D of the Notice states "[p]ublications of international applications filed before November 29, 2000...do not have a § 102(e) date at all." (See, the Notice, section D, page 3 (signed December 11, 2002)). Applicant respectfully requests the withdrawal of this rejection.

The Examiner also rejected claims 122, 123, 127, and 128 under 35 U.S.C. § 103(a) as being unpatentable over Paul or Tsitsopoulos. Applicant submits that the rejection over claims 122, 123, 127, and 128 is rendered moot at least in view of the patentability of independent claims 121 and 126, which Applicant submits are in condition for allowance and from which the rejected dependent claims depend either directly or indirectly.

Applicant submits that independent claims 121 and 126 are patentable and that dependent claims 122-125, 127-130, and 203-210 dependent from independent claims 121 and 126, or claims dependent therefrom are patentable at least due to their dependency from an allowable independent claim. Applicant submits that the rejections of these claims over the art of record have been overcome. Applicant also submits that new claims 211-214 are allowable over art of record at least due to their dependency from an allowable independent claim.

In view of the foregoing remarks, it is respectfully submitted that the claims, as amended, are patentable. Therefore, it is requested that the Examiner reconsider the outstanding rejections in view of the amendments to the claims and preceding comments. Issuance of a timely Notice of Allowance of the claims is earnestly solicited.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this reply, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-1066.

Respectfully submitted,

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CHANGES TO THE CLAIMS

Please amend the claims as follows:

121. (Amended) A method for forming an interbody spinal implant having a plurality of bone engaging structures for insertion between adjacent vertebral bodies of a human spine, the method comprising the steps of:

providing the implant comprising a leading end for introduction of the spinal implant into the spine, an opposite trailing end, and spaced apart sides therebetween, opposite upper and lower surfaces between said leading and trailing ends and said spaced apart sides, said upper surface adapted for placement toward the bone of one of the vertebral bodies and said opposite lower surface adapted for placement toward the bone of the other of the vertebral bodies when said implant is placed between the adjacent vertebral bodies; and

forming a plurality of surface projections as part of the upper and lower surfaces of the implant, each of the surface projections having a base, at least two of the surface projections each having~~the surface projections being formed to have~~ at least one forward facet directed at least in part toward the leading end and at least one rearward facet directed at least in part toward the trailing end, said forward facet and rearward facet being formed to have a length and a slope, the length of said forward facet being longer than the length of said rearward facet, the slope of said rearward facet being steeper than the slope of said

forward facet, each of said at least two surface projections being formed to have opposed side facets extending from the base and being directed generally toward said spaced apart sides of the implant, respectively, said side facets being located between said forward facet and said rearward facet of each of said at least two surface projections, said side facets converging toward each other in a direction away from the base, said side facets having a maximum width therebetween at the base, the base of at least one of said at least two surface projections being spaced apart from a base of another of said surface projections by a distance no greater than one-half the maximum width of at least one of said at least two surface projections, said forward facets of said at least two surface projections facing the same direction of said projections.

126. (Amended) A method for forming an interbody spinal implant having an exterior surface with a plurality of bone engaging structures for insertion between adjacent vertebral bodies of a human spine, the method comprising the steps of:

providing the implant comprising a leading end for introduction of the spinal implant into the spine, an opposite trailing end, spaced apart sides therebetween, and a mid-longitudinal axis passing through the leading and trailing ends, opposite upper and lower surfaces between said leading and trailing ends and said spaced apart sides, said upper surface adapted for placement toward the bone of one of the vertebral bodies and said opposite lower surface adapted for placement toward the bone of the other of the vertebral bodies when the implant is placed between the adjacent vertebral bodies; and

forming surface projections as part of the upper and lower surfaces of the implant, at least two of said surface projections each having at least one forward facet directed at least in part toward the leading end and at least one rearward facet directed at least in part toward the trailing end, said forward facet and said rearward facet having a length and a slope, the length of said forward facet being longer than the length of said rearward facet, the slope of said rearward facet being steeper than the slope of said forward facet, said at least two of said surface projections having opposed side facets between said forward facet and said rearward facet, said side facets having at least a first portion in a plane passing through and being at an angle to the mid-longitudinal axis of the implant, said forward facets of said at least two of said surface projections facing the same direction.

204. (Amended) The method of claim 203, further comprising the step of combining the implant with at least one of harvested bone, bone morphogenetic proteins, hydroxyapatite, and genes coding for the production of bone.
206. (Amended) The method of claim 205, further comprising the step of combining the implant with at least one of harvested bone, bone morphogenetic proteins, hydroxyapatite, and genes coding for the production of bone.
208. (Amended) The method of claim 207, further comprising the step of combining the implant with at least one of harvested bone, bone morphogenetic proteins, hydroxyapatite, and genes coding for the production of bone.
210. (Amended) The method of claim 209, further comprising the step of combining the implant with at least one of harvested bone, bone morphogenetic proteins,

hydroxyapatite, and genes coding for the production of bone.